



DOCKET NO. BMS-2599/PH-7094-B

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Paul J. Gilligan, et al.

Application No.: 10/803,415

Filing Date: March 18, 2004

For: PYRAZOLOTRIAZINES AS CRF ANTAGONISTS

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: May 14, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

### INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

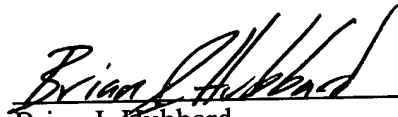
- ☒ In view of the voluminous nature of reference 15, and the likelihood that this reference is available to the Examiner, a copy is not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references **1-12, 47-60 and 63-73** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/543,290**, filed **April 5, 2000**; copies of references **13, 61-62 and 74-75** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/990,138**, filed **November 21, 2001**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date:

*May 14, 2004*

  
\_\_\_\_\_  
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Sheet 1 of 8

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. BMS-2599/PH-7094-B		Application No. 10/803,415	
	Applicant Paul J. Gilligan, et al.			
	Filing Date March 18, 2004		Group Not Yet Assigned	
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
	1	Deeb, A., et al., "Preparation of naphtha[2,1-e]pyrazolo[5,1-c][1,2,4]triazine, dipyrazolo[5,1-c:3',4'-e][1,2,4]triazines and pyrazolo-[1,5-c][1,2,4]triazine derivatives," <i>Collect. Czech. Chem. Commun.</i> , <b>1990</b> , 55, 2790-2794		
	2	Ege, G., et al. "Reactions with diazoazoles. Part IV. (1). [7+2]- and [11+2]-cyclocondensation reactions of diazoazoles with acyltriphenylphosphonium methylides to azolo[5,1-c][1,2,4]triazines," <i>J. Heterocyclic Chemistry</i> , June <b>1981</b> , 18(4), 675-677		
	3	Gray, E.J., et al., "Triazines and related products. Part 21. Cyclisation of 3-amino-5-hydrazinopyrazole and 3-amino-5-hydrazino-1,2,4-triazole to azolo-[5,1-c][1,2,4]triazines," <i>J. Chemical Society</i> , <b>1978</b> , 885-888		
	4	Ibrahim, et al., <i>Arch. Pharm. (Weinheim)</i> , <b>1987</b> , 320, 487-491		
	5	<i>Journal of Med. Chem.</i> , <b>1981</b> , 24, 610-613		
	6	Joshi, et al., <i>J. Prakt. Chemie</i> , <b>1979</b> , 321(2), 341-344		
	7	Kandeel, E.M., et al., "Reactions with heterocyclic amidines...", <i>Chemical Abstracts Service, Columbus, OH</i> , Accession No. 99:122411, RN87031-23-0 & <i>Arch. Pharm. (Weinheim, Ger.)</i> , <b>1983</b> , 316(8), 713-718		
	8	Maquestiau, et al., <i>Bull. Soc. Belg.</i> , <b>1992</b> , 101(2), 131-136		
	9	Ramiz, M.M.M., et al., "Studies on amino-azoles; synthesis of...", <i>Chemical Abstracts Service, Columbus, OH</i> , Accession No. 112:35748, RN124612-21-1 & <i>Arch. Pharm. (Weinheim, Ger.)</i> , <b>1989</b> , 322(9), 557-560		
	10	Senga, K., et al., "Synthesis and enzymic activity of various substituted pyrazolo[1,5-a]-1,3,5-triazines as adenosine cyclic 3',5'-phosphate phosphodiesterase inhibitors," <i>J. Med. Chem.</i> , <b>1982</b> , 25, 243-249		
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	11	Springer, et al., <i>J. Med. Chem.</i> , 1976, 19(2), 291-296	
	12	Strohmeyer, T.W., et al., "New synthesis of 2,4-dialkyl...", <i>J. Het. Chem.</i> , 1985, 22(7), 7-10	
	13	<i>J. Het. Chem.</i> , 1985, 22, 610	
	14	Arató, M., et al., "Elevated CSF CRF in suicide victims," <i>Biol. Psychiatry</i> , 1989, 25, 355-359	
*	15	Armarego, W.L.F., Purification of Laboratory Chemicals, 3 <sup>rd</sup> Ed. <i>Pergamon Press</i> , NY, 1988	
	16	Banki, C.M., et al., "CSF corticotrophin-releasing factor-like immunoreactivity in depression and schizophrenia," <i>Am. J. Psychiatry</i> , 1987, 144(7), 873-877	
	17	Battaglia, G., et al., "Characterization of corticotrophin-releasing factor receptor-mediated adenylate cyclase activity in the rat central nervous system," <i>Synapse</i> , 1987, 1, 572-581	
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	20	Blalock, J.E., "A molecular basis for bidirectional communication between the immune and neuroendocrine systems," <i>Physiological Reviews</i> , 1989, 69(1), 1-32	
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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.

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	21	Britton, D.R., et al., "Intraventricular corticotrophin-releasing factor enhances behavioral effects of novelty," <i>Life Sci.</i> , <b>1982</b> , <i>31</i> , 363-367
	22	Britton, K.T., et al., "Corticotropin releasing factor and amphetamine exaggerate partial agonist properties of benzodiazepine antagonist Ro 15-1788 in the conflict test," <i>Psychopharmacology</i> , <b>1988</b> , <i>94</i> , 306-311
	23	Britton, K.T., et al., "Chlordiazepoxide attenuates response suppression induced by corticotrophin-releasing factor in the conflict test," <i>Psychopharmacology</i> , <b>1985</b> , <i>86</i> , 170-174
	24	DeSouza, E.B., "CRH defects in alzheimer's and other neurologic diseases," <i>Hosp. Practice</i> , <b>1988</b> , <i>23</i> , 59-71
	25	DeSouza, E.B., "Corticotropin-releasing factor receptors in the rat central nervous system: characterization and regional distribution," <i>J. Neurosci.</i> , <b>1987</b> , <i>7(1)</i> , 88-100
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	28	France, R.D., et al., "CSF corticotrophin-releasing factor-like immunoactivity in chronic pain patients with and without major depression," <i>Biol. Psychiatry</i> , <b>1988</b> , <i>23</i> , 86-88
	29	Gold, P.W., et al., "Psychiatric implications of basic and clinical studies with corticotrophin-releasing factor," <i>Am. J. Psychiatry</i> , <b>1984</b> , <i>141(5)</i> , 619-627
	30	Gold, P.W., et al., "Responses to corticotrophin-releasing hormone in the hypercortisolism of depression and cushing's disease," <i>New Eng. J. Med.</i> , <b>1986</b> , <i>314</i> , 1329-1335
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	<b>35</b>	Morley, J.E., "Minireview neuropeptides: conductors of the immune orchestra," <i>Life Sci.</i> , <b>1987</b> , 41, 527-544
	<b>36</b>	Lee, J.J., et al., "Synthesis of aryl $\omega$ -(1-methyl-5-imidazolyl and 1H-5-tetrazolyl)alkyl ketones [1]," <i>J. Het. Chem.</i> , <b>1998</b> , 35, 81-87
	<b>37</b>	Munson, et al., "LIGAND: A versatile computerized approach for characterization of ligand-binding systems," <i>Anal. Biochem.</i> , <b>1980</b> , 107, 220-239
	<b>38</b>	Nemeroff, C.B., et al., "Reduced corticotrophin releasing factor binding sites in the frontal cortex of suicide victims," <i>Arch. Gen. Psychiatry</i> , <b>1988</b> , 45, 577-579
	<b>39</b>	Nemeroff, C.B., et al., "Elevated concentrations of CSF corticotrophin-releasing factor-like immunoreactivity in depressed patients," <i>Science</i> , <b>1984</b> , 226, 1342-1344
	<b>40</b>	Remington's Pharmaceutical Sciences, 17 <sup>th</sup> Ed., <i>Mack Publishing Co., Easton, PA</i> , <b>1985</b> , page 1418
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	<b>41</b>	River, J., et al., "Characterization of rat hypothalamic corticotrophin-releasing factor," <i>Proc. Nat. Acad. Sci. USA</i> , <b>1983</b> , <i>80</i> , 4851-4855
	<b>42</b>	Sapolsky, R.M., "Hypercortisolism among socially subordinate wild baboons originates at the CNS level," <i>Arch. Gen. Psychiatry</i> , <b>1989</b> , <i>46</i> , 1047-1051
	<b>43</b>	Swerdlow, N.R., et al., "Corticotropin-releasing factor potentiates acoustic startle in rats: blockade by chlordiazepoxide," <i>Psychopharmacology</i> , <b>1986</b> , <i>88</i> , 147-152
	<b>44</b>	Vale, W., et al., "Characterization of a 41-residue ovine hypothalamic peptide that stimulates secretion of corticotrophin and $\beta$ -endorphin," <i>Science</i> , <b>1981</b> , <i>213</i> , 1394-1397
	<b>45</b>	Vale, W., et al., "Chemical and biological characterization of corticotrophin releasing factor," <i>Rec. Prog. Horm. Res.</i> , <b>1983</b> , <i>39</i> , 245-270
	<b>46</b>	Valentino, R.J., et al., "Effects of CRF on spontaneous and sensory-evoked activity of locus coeruleus neurons," in "Corticotropin-Releasing Factor: Basic And Clinical Studies Of A Neuropeptide," De Souza, E.B., et al. (Eds.), <i>CRC Press</i> , <b>1990</b> , 217-231
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Examiner Initial		Document No.	Date	Name	Class	Subclass	
	47	3,910,907	10/07/75	O'Brien, et al.			
	48	3,920,652	11/18/75	Springer, et al.			
	49	3,995,039	11/20/76	Rooney, et al.			
	50	4,021,556	05/03/77	Springer, et al.			
	51	4,567,263	01/28/86	Eicken, et al.			
	52	4,621,556	11/11/86	Soltysiak, et al.			
	53	4,892,576	01/09/90	Kruger, et al.			
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	56	6,060,478	05/09/00	Gilligan, et al.	514	258	
	57	6,124,289	09/26/00	He, et al.	514	245	
	58	6,136,809	10/24/00	Gilligan, et al.	514	258	
	59	6,191,131	02/20/01	He, et al.	514	246	
	60	6,194,410	02/27/01	Bos, et al.	514	246	
	61	5,397,774	03/14/95	Nugent, et al.			
	62	5,484,760	01/16/96	Bussler, et al.			
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Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	63	WO 99/38868 A	08/05/99	PCT			
	64	0 269 859	10/18/95	EPO			
	65	0 374 448	06/27/90	EPO			
	66	0 511 528	02/16/94	EPO			
	67	0 521 622	08/13/97	EPO			
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Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	80	WO 92/10098	06/25/92	PCT			
	81	WO 94/09017	04/28/94	PCT			
	82	WO 95/10506	04/20/95	PCT			
	83	0 594 149 A3	04/27/94	EPO			
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